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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,649	12/04/2006	Annette Graneli	24793-53	2637
24256 DINSMORE &	7590 03/09/201 SHOHL LLP	EXAMINER		
1900 CHEMED	CENTER	JUNG, UNSU		
255 EAST FIFTH STREET CINCINNATI, OH 45202			ART UNIT	PAPER NUMBER
			1641	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
Office Action Comment	10/552,649	GRANELI ET AL.				
Office Action Summary	Examiner	Art Unit				
	UNSU JUNG	1641				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) Responsive to communication(s) filed on 28 De	ecember 2000					
	Responsive to communication(s) filed on <u>28 December 2009</u> .  This action is <b>FINAL</b> .  2b) This action is non-final.					
<del>'=</del>	<i>/</i>					
•						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims						
4)⊠ Claim(s) <u>1-13,15-22,33-39 and 41-62</u> is/are pe	4) Claim(s) <u>1-13,15-22,33-39 and 41-62</u> is/are pending in the application.					
	4a) Of the above claim(s) <u>6,7,9-13,15-22,33-39 and 41-62</u> is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1-5 and 8</u> is/are rejected.	· ·· ·· ·					
7) Claim(s) is/are objected to.	·					
· · · · · · · · · · · · · · · · · · ·	election requirement					
8) Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9)☐ The specification is objected to by the Examiner.						
10)⊠ The drawing(s) filed on <u>07 October 2005</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11)⊠ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
<u>.</u>						
	12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)						
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da					
) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date 12/28/2009.  5) Notice of Informal Patent Application 6) Other:						

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### **DETAILED ACTION**

## Response to Amendment

1. Applicant's amendments in the reply filed on December 28, 2009 have been acknowledged and entered. The reply included amendments to claims 1-3, 5, 8, 11-13, 33, 39, 41, 45, and 55 and cancellation of claims 14, 23-32, and 40.

#### Status of Claims

2. Claims 1-13, 15-22, 33-39, and 41-62 are pending, claims 6, 7, 9-13, 15-22, 33-39, and 41-62 have been withdrawn from consideration, and claims 1-5 and 8 are currently under consideration for patentability under 37 CFR 1.104.

## **Priority**

3. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. The instant application is a national phase under 35 U.S.C. 371 of PCT International Application No. PCT/SE2004/000555, filed on April 7, 2004 and claims priority under 35 U.S.C. §119 to Application Serial No. 60/461,197 filed April 9, 2003.

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of Sweden 0301038-6 has been filed on April 7, 2003 in the instant application.

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#### Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on December 28, 2009 has been considered by the examiner.

## Oath/Declaration

5. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: Non-initialed and/or non-dated alterations have been made to the oath or declaration dated August 18, 2006. See 37 CFR 1.52(c).

Applicant's response that new Declaration will be submitted has been acknowledged. The objection of the Declaration has been maintained until the new Declaration is received.

## Objections Withdrawn

- 6. The objection of the abstract has been withdrawn in view of the amended abstract in the reply filed on December 28, 2009.
- 7. The objection of claims 1 and 2 has been withdrawn in view of the amended claims 1 and 2 in the reply filed on December 28, 2009.

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# Claim Objections

8. Claim 5 is objected to because of the following informalities: the term "said linker" in lines 3 and 4 should be corrected to "vesicle-attached linkers" in order to clearly provide antecedent basis for the term "said linker" in lines 3 and 4 of claim 5 since there are two types of linkers recited in the independent claim 1. Appropriate correction is required.

# Rejections Withdrawn

9. The rejection of claims 2 and 8 under 35 U.S.C. 112, second paragraph has been withdrawn in view of amended claims 2 and 8 in the reply filed on December 28, 2009.

## Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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11. Claims 1-5 and 8 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by Bredehorst et al. (WO 02/081739 A2, published Oct. 17, 2002 and filed Apr. 9, 2001) (hereinafter "Bredehorst").

Bredehorst anticipates instant claims by teaching a biologically functional surface immobilized multilayer structure comprising a plurality of vesicles (affinity liposomes) sufficiently spaced apart from the surface (see entire document, particularly p5, lines 17-27 and Fig.'s 1-4). The vesicles are directly attached to the structure by surface-immobilized linkers (analyte and/or capture oligonucleotides) with vesicle-attached linkers (affinity components) and optionally by vesicle-attached linkers to another vesicle (Fig. 4). The vesicles comprise the biologically active compounds (p5, lines 17-27), which provide the structure with its biological functionality.

With respect to claim 2, Bredehorst teaches that the vesicles are directly attached to the surface immobilized linkers with vesicle-attached linkers so that at least two vesicles are attaché to each surface immobilized linker (Fig. 4). The vesicle attached linker is adapted to bind to the surface immobilized linker but not to another vesicle attached linker (Fig. 4).

With respect to claim 3, Bredehorst teaches that the vesicles are attached to the structure by a) the surface immobilized linker and b) vesicle-attached linkers, so as to provide said structure with two or more of vesicle layers (Fig. 4).

With respect to claims 4 and 8, Bredehorst teaches that the linkers comprise oligonucleotides, and the binding of a linker to another linker is mediated through

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hybridization of the oligonucleotides (p8, lines 12-33), which is essentially sequence specific.

With respect to claim 5, Bredehorst teaches that the vesicle attached linkers are attached to the vesicles via a covalent bond to the vesicle via a functionalized group comprised in said linker (p10, line 30-p11, line 10).

## Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-5 and 8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 10/590,877. Although the conflicting claims are not identical,

they are not patentably distinct from each other because each recites a biologically functional surface immobilized multilayer structure comprising a plurality of vesicles sufficiently spaced apart from the surface. The vesicles are directly attached to the structure by surface-immobilized linkers with vesicle-attached linkers and optionally by vesicle-attached linkers to another vesicle. The vesicles comprise the biologically active compounds, which provide the structure with its biological functionality. Therefore, the claims of the copending Application anticipate the claims of instant application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

## Response to Arguments

14. <u>Claims 1-5 and 8 are rejected under 35 U.S.C. 102(a) and 102(e) as being</u> anticipated by Bredehorst

Applicant's arguments filed on December 28, 2009 have been fully considered but they are not persuasive essentially for the reasons of record and arguments addressed herein.

Applicant's argument that Bredehorst fails to disclose vesicles directly attached to the structure by surface-immobilized linkers with vesicle-attached linkers has been fully considered but is not found persuasive essentially for the reasons of record. As stated in the previous Office Action dated June 25, 2009 (item 13), Bredehorst anticipates instant claims by teaching a biologically functional surface immobilized multilayer structure comprising a plurality of vesicles (affinity liposomes) sufficiently spaced apart from the surface (see entire document, particularly p5, lines 17-27 and

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Fig.'s 1-4). The vesicles are directly attached to the structure by surface-immobilized linkers (analyte and/or capture oligonucleotides) with vesicle-attached linkers (affinity components) and optionally by vesicle-attached linkers to another vesicle (Fig. 4). The vesicles comprise the biologically active compounds (p5, lines 17-27), which provide the structure with its biological functionality. In contrast to applicant's assertion, Bredehorst does teach each and every element currently recited in claim 1.

# 15. <u>Double Patenting Rejection</u>

Applicant's arguments filed on December 28, 2009 have been fully considered but they are not persuasive essentially for the reasons of record and arguments addressed herein.

Applicant's request to withdrawn the obviousness-type double patenting rejection because the co-pending application requires a specific oligonucleotide having two hydrophobic anchoring moieties that is not required nor obvious over the present claims has been considered but is not found persuasive essentially for the reasons of record. As stated in the previous Office Action dated June 25, 2009 (item 15), claims 16-22 of the copending Application No. 10/552,649 recite a biologically functional surface immobilized multilayer structure comprising a plurality of vesicles sufficiently spaced apart from the surface. The vesicles are directly attached to the structure by surface-immobilized linkers with vesicle-attached linkers and optionally by vesicle-attached linkers to another vesicle. The vesicles comprise the biologically active compounds, which provide the structure with its biological functionality. The instant claims further

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recites that linkers include oligonucleotides and have at least one hydrophobic anchoring moiety (claims 4 and 5) and the copending application recites oligonucleotide having two hydrophobic anchoring moieties (claim 1) as acknowledged by the applicant. Since the more narrow claims of the copending application (oligonucleotide having two hydrophobic anchoring moieties) encompasses the broader claims of the instant application linkers including oligonucleotides or have at least one hydrophobic anchoring moiety, the claims of the copending Application anticipate the claims of instant application.

16. Since the prior art fulfills all the limitations currently recited in the claims, the invention as currently recited would read upon the prior art.

### Conclusion

- 17. No claim is allowed.
- 18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to UNSU JUNG whose telephone number is (571)272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Unsu Jung/ Unsu Jung Primary Examiner

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